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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/552,272	04/19/2000	Li Fang	913.6600CIP	3198
35811	7590	10/25/2004	EXAMINER	
IP DEPARTMENT OF PIPER RUDNICK LLP ONE LIBERTY PLACE, SUITE 4900 1650 MARKET ST PHILADELPHIA, PA 19103			EPPS FORD, JANET L	
			ART UNIT	PAPER NUMBER
			1635	

DATE MAILED: 10/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/552,272	Applicant(s) FANG ET AL.	
	Examiner Janet L. Epps-Ford, Ph.D.	Art Unit 1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 August 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,5,6,10 and 14-57 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,5,6,10 and 14-57 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 4/19/04 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Response to Arguments

2. Claims 16-57 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record set forth in the Official Action mailed 11-19-02.

Applicant's arguments filed 8-06-04 have been fully considered but they are not persuasive. Applicants traverse the instant rejection on the grounds that the instant claims recite adequate structure and function of the claimed vectors, which is well supported and adequately defined in the original specification (see page 9, 3rd paragraph of response filed 8-06-04). First it is noted that Applicants have not amended the instant claims to recite any structural information. The claimed invention, which is drawn to biomolecules and the use thereof, is described only by function.

According to Applicants "[P]ossession of the claimed invention can be shown using words, structures, figures, diagrams and formulas that set forth all of the elements of the claimed invention." However, since the instant claims are drawn to a nucleic acid sequence, more than just functional language is required since there is no obvious correlation between the recited function and the corresponding nucleic acid structure associated with said function. See MPEP § 2163, which states "[A] biomolecule sequence described only by a functional characteristic,

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without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.”

Claims 16-57 require the structure of a first cold shock inducible gene, or a first and second cold shock inducible gene, and/or a cold box, and/or a down stream box. Although certain structures corresponding to these functional elements are disclosed in the specification as filed. The instant claims are not limited to those particular first and second cold shock inducible genes, and/or the cold box sequences, and/or the down stream box sequences described in the specification as filed. Absent evidence to the contrary, the instant claims encompass a genus of nucleic acid molecules that reads on all polymorphic and allelic variants of said first and/or second cold shock inducible genes, cold box sequences, and/or a down stream box sequences that are beyond the scope of the instant disclosure.

According to Applicants, the vectors recited in claim 16 are described, for example, in the specification at page 28, line 8, through page 29, line 14. However, the instant claims are not limited to those vectors set forth in the specification as filed. Additionally, Applicants refer to a down stream box and a cold box as described in the specification as filed. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

As stated in the prior Office Action, the instant claims read on a broad genus of nucleic acid molecules that function to prolong the expression of a cold shock inducible gene, wherein said isolated nucleic acid molecule “is mediated by a portion” a 5’-UTR of a cold shock inducible gene, sequences that are substantially homologous to said cold shock inducible genes,

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including all polymorphic and allelic variants of nucleic acid molecules that are mediated by a portion of a 5'-UTR of a cold shock inducible gene, and sequences isolated from any organism. According to Applicants, the phrase "at least a portion of a 5'UTR of a cold shock inducible gene," is a regulatory element. However, the instant claims are not limited to wherein said "at least a portion of a 5'UTR" corresponds to a regulatory element. As stated above, "[A]lthough the claims are interpreted in light of the specification, limitations from the specification are not read into the claims." See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Furthermore, there is no structure recited in the instant claims. Moreover, Applicant's describes only the 5'-UTR of the cold shock inducible genes according to the *cspA*, *cspB*, and *csdA* genes. Applicant's description of the nucleic acid molecules according to the *cspA*, *cspB*, and *csdA* genes, is not commensurate in scope with the broad genus of nucleic acid molecules encompassed by the instant claims, such that the ordinary skilled artisan can use the description set forth in the specification as filed to predict the structures of all members of the broad genus of molecules encompassed by the instant claims. It is evident that further experimentation would be required in order to identify those sequences that are substantially homologous to the sequences of (for example) the *cspA*, *cspB*, and *csdA* genes, and furthermore to identify those substantially homologous sequences that function to prolong the expression of a cold shock inducible gene, or wherein said sequence functions to enhance translation of a gene under conditions that elicit a cold shock response in a bacterium. The fact that further experimentation is required indicates that the full scope of the claimed invention was not reduced to practice at the time of filing of the instant application.

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Possession cannot be demonstrated by a means for isolating an invention, [A]n applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. Possession may be shown in a variety of ways including description of an actual reduction to practice, or by showing that the invention was "ready for patenting" such as by the disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that applicant was in possession of the claimed invention." See the January 5, 2001 (Vol. 66, No. 4, pages 1099-1111) Federal Register for the Guidelines for Examination of Patent Applications Under the 35 USC 112 ¶ 1.

As stated in the prior Office Action, the full scope of the claimed invention was not "ready for patenting" at the time the invention was filed. Therefore, applicant was not in possession of the full scope of the claimed invention at the time of filing of the instant application.

Response to Arguments

3. Claims 1, 5-15 and 57 remain rejected as being anticipated by Goldstein et al. for the reasons of record set forth in the Official Action mailed 9-13-01; Claims 1, 5-6 and 57 remain rejected as being anticipated by Oppenheim et al. (US Patent No. 5,726,039) or Oppenheim et al. (US Patent No. 5,654,169), for the reasons of record set forth in the Official Action mailed 4-07-04.

4. Applicant's arguments filed 8-06-04 have been fully considered but they are not persuasive. Applicants traverse the instant claims on the grounds that neither Goldstein nor

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Oppenheim disclose the particular sequences recited in claims 1, 5, 6, 10, 14, 15, and 57. According to Applicants these references describe the nucleic acids which contain the entire 5'-UTR, or which contain additional elements, such as Shine-Dalgarno sequences or promoters, that would materially change the nature of the claimed isolated nucleic acid molecules. Although the sequences recited in the cited references contain additional elements, the sequence recited in Goldstein and Oppenheim et al. read on the claimed invention since the instant isolated nucleic acid molecules "consist essentially" of nucleotides 1-11 of SEQ ID NO: 55, nucleotides 56-117 of SEQ ID NO: 55, nucleotides 123-135 of SEQ ID NO: 55, SEQ ID NO: 49 or SEQ ID NO: 50, and Applicants have not defined what specified elements would materially affect the basic and novel characteristic(s) of the claimed invention. Moreover, since there is no definition of the term "consisting essentially of" recited in the specification as filed, this term is interpreted as open claim language, equivalent to the term "comprising." Absent evidence to the contrary, the nucleic acid structures disclosed in both Goldstein et al. and Oppenheim et al., corresponding to the 5'UTR of the *cspA* cold shock inducible gene of *E. coli*, do not materially affect the basic characteristics of the claimed invention since the *cspA* gene functions as a cold shock inducible gene as recited in the instant claims, and furthermore the 5'UTR of the *cspA* gene comprises (i.e. consists essentially of) the entire sequence of SEQ ID NO: 55 of the instant application. Applicant's arguments do not take the place of evidence that the nucleic acid molecules disclosed by Goldstein et al. and Oppenheim et al. do not read on the isolated nucleic acid molecules of the instant claims.

Conclusion

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Ford, Ph.D. whose telephone number is 571-272-0757. The examiner can normally be reached on Monday-Saturday, Flex Schedule.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on 571-272-0760. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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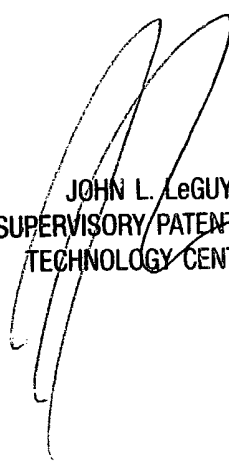
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Janet L. Epps-Ford, Ph.D.
Patent Examiner
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